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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/444,934	05/22/95	LAWN	R MSM101CONTC

EXAMINER
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HM21/0217

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JACOBSON, D.	PAPER NUMBER
ART UNIT	26

1652

DATE MAILED: 02/17/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on Feb. 18, 1997

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 4-6, 8, 20, 21, 23-25, 27-29, 31-41 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☒ Claim(s) 4-6, 8 is/are allowed.  
☒ Claim(s) 20, 21, 23-25, 27-29, 31-36, 38-41 is/are rejected.  
☒ Claim(s) 37 is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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Claims 4-6, 8, 20-21, 23-25, 27-29, and 31-41 are pending in the present application.

The previous 35 U.S.C. 112, first paragraph, rejections of claims 4-6, 8, and 30 have been withdrawn in light of applicants' amendments to the claims.

Claims 20-21, 27-29, 31-36, and 38-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 20 is drawn to a molecule that has the sequence from amino acid one to an amino acid between residues 219 and 263. The specification also does not describe a molecule that ends at any point between residues 219 and 263.

Claims 31-36 and 38-41 are drawn to a tissue factor molecule comprising amino acid one to amino acid 219. The word "comprising" is open language and encompasses molecules that include additional residues. For example the claims include molecules that have an amino acid residue between residues 220 and 263.

As discussed above, the specification discloses tissue factor variants that lack residues 220-242 (page 13), have specific insertions (page 12), have specific point mutations (page 16), or have altered glycosylation sites (page 16). The specification does not describe other tissue factor variants. Claims to other variants constitute new matter.

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In their amendment filed Feb. 18, 1997, applicants traverse the previous new matter rejection on the grounds that the specification discloses many more tissue factor variants listed in the above rejection. Applicants argue that the specification conveys that the tissue factor variants contemplated are not limited to substitutions, insertions, deletions, or altered glycosylation sites in the alternative. Applicants further assert that each of the classes of variants includes numerous alterations. Applicants argue that use of the word "class" and "involving" in the specification implies deletion of the transmembrane regions and deletion of other amino acids. Each of these arguments has been fully considered but is not deemed to be persuasive.

As discussed above, the specification describes deletion of the transmembrane domain, residues 220 to 242. Applicants have not *specifically* suggested other deletion variants. It is true that, following the methods described in the specification, one could conceivably be able to construct other deletion variants if one had the motivation to do so. Applicants have not provided any specific motivation to construct other deletion variants. In order to be enabling, a specification must stand on its own to suggest the claimed invention. Applicants have suggested that one to thirty residues may be deleted, but without reference to particular residues. The mature tissue factor protein is 263 amino acids long and thus contains many possible fragments one to thirty amino acids long. One would need to construct all of the possible deletion mutants to identify those proteins that retain biological activity. Such would require undue experimentation.

Applicants have argued that the standard regarding what is supported by the specification requires that the specification convey that the inventor was in possession of the invention as is

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now claimed. Applicants refer to MPEP 2163.02, which states that the subject matter need not be described literally. This argument has been considered. However, the specification does not clearly and specifically suggest constructing the claimed tissue factor variants. Should the present application become an issued patent, it would not suggest to one of skill in the art to construct the claimed deletion variants, nor would it provide motivation to construct such variants.

Amendments to claims that recite elements without support in the original disclosure do not meet the criteria of 35 U.S.C. 112, first paragraph. New matter also includes adding specific limitations after a broader original disclosure. An objective standard for determining the written description requirement is, "Does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed?" (MPEP 2163.02) In addition, if a claim is amended to include subject matter or limitations not present in the application as filed, one should conclude that the claimed subject matter is not described in that application.

Applicants' amendments to the claims essentially introduce limitations. "[I]ntroducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph." The MPEP provides an example of an applicant not entitled to the benefit of a parent filing date when the claim was directed to a subgenus. The parent application contained a generic disclosure. A specific example in the child application that fell within the recited range. The court held that subgenus range was not described in the parent application. "Whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is

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necessarily described by a genus encompassing it and a species upon which is reads.” (MPEP 2163.05(b))

Therefore, because applicants have not specifically disclosed other deletion variants of the tissue factor protein, as is now claimed, claims to such are deemed to constitute new matter.

Claims 4-6, 8, 20-21, 23-25, 27-29, and 31-41 are free of prior art. *Claims 4-6, and 8 are allowable.* Claim 37 is objected to as depending from a rejected claim. It is noted that claims to specific tissue factor variants lacking residues 220-242, or that have specific insertions, point mutations, or altered glycosylation sites may be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dian C. Jacobson whose telephone number is (703) 308-2973. The examiner can normally be reached Monday, Tuesday, and Thursday from 7:30 to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at (703) 308-4216. The official FAX number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Dian C. Jacobson*  
DIAN C. JACOBSON  
PRIMARY EXAMINER  
GROUP 1800-1600